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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,042	11/30/2001	Hermona Soreq	1567/66364/JPW/FHB	6063

7590 12/03/2003

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EXAMINER	
CHISM, BILLY D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,042	SOREQ ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on th cov r she t with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *18-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☒ Claim(s) *1-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-17, in Paper No. 10, is acknowledged. The traversal is on the ground(s) that all groups are not independent and that "Groups I-XI are necessarily related." This was not found persuasive for the following reasons. Group I was decided to be independent from Groups VI-VII for the reasons given in the Restriction of Paper No. 10, wherein as is stated in the MPEP §806.04 the claimed inventions of the Groups I and VI-VII are not capable of use together. Groups II-IV, VVI-VII and VIII-XI were decided to be independent wherein again the claimed inventions are incapable of use together and under the MPEP §806.04 are to be restricted as independent claims. Group V was determined to be independent from Groups II-IV and VIII-XI for the reasons set forth in Paper No. 10 and wherein under MPEP §806.04 are to be restricted as independent claims wherein the Group V is incapable of use together with the methods of Groups II-IV and VIII-XI.

Applicants argue that there are two criteria for a proper restriction requirement. The first criterion was established in Paper No. 10 and reaffirmed as explained above. The second criterion requires a serious burden on the Examiner for searching. The Examiner established in Paper No. 10 that the additional inventions would require additional searches since the search for one Group would not be inclusive of any other Group, therefor a burden upon the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

1. Claims 1-4, 7, 9-17 are objected to because of the following informalities:

a. Claims 1-4, 7, 12 and 14 are objected to for the improper identification of a sequence, wherein each claim recites "SEQ ID: No....", however, the proper recitation should read "SEQ ID NO:".

b. Claim 1 requires the term "A" to be inserted before the term "regulatory".

c. Claims 2 and 4 require the term "The" to identify the peptide being claimed. Appropriate correction is required.

d. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 does not further limit claim 3, wherein the terms "comprising" of claim 3 and "having" of claim 4 are considered open language, therefore, claim 4 is merely a non-limiting repeat of claim 3.

e. Claims 5 and 6 cite "A". The Examiner suggests that the claims be amended to read as follows for claim 5, "The peptide according to claim 3, which is linear" and claim 6 should read as follows, "The peptide according to claim 3, which is cyclic".

f. Claims 7, and 9-17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 7 and 9-10 recite a product and no tangible limitation, wherein the prophetic term "capable" does not lend limitation to the metes or bounds. Therefore the claims are only to the peptide of the respective parent claims. Claims 11-17 are merely intended use claims of the peptides of

their respective parent claims and therefore lack any further limitation to the respective parent claims.

g. Claims 7-17 are objected to for the use of the term "A" when referencing the peptides of previous claims. The term should be deleted and the term "The" inserted.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected wherein it is unclear if the peptide one of cell growth activity OR one cell differentiation activity OR if the peptide must have at least one of each combined. The use of the term "of" in the phrase "at least one [of] cell growth and cell differentiation activity" is unclear. Also, Claim 1 is rejected for the indefinite use of the term "activity" wherein it is unclear what the definition and metes and bounds of the term are, i.e. cellular use of water is an activity that occurs during differentiation; thus, if the product promotes or induces differentiation then the term "activity" could be deleted to more clearly specify what is claimed in the invention. Claim 1 is rejected for the improper Markush language wherein the language "having at least one of..." is vague and unclear (see example below). Claim 1 is also rejected for vague language wherein it is unclear if SEQ ID NO: 1 is the sequence for acetylcholinesterase or if SEQ ID NO: 1 is the sequence for the regulatory peptide.

Claim 2 is rejected for the indefinite recitation of "substantially" wherein the term is vague and offers no boundaries for the metes and bounds for the claimed regulatory peptide.

Claims 7 and 9-10 are rejected wherein the claims do not recite a limitation by the use of the indefinite term "capable" wherein the term "capable" is suggestive and prophetic by nature.

Claim 8 is rejected for the indefinite recitation of the phrase, "which is any one of hematopoietic stem cell growth and differentiation regulatory peptide." The peptide can be a specific type of peptide, i.e., differentiation regulatory peptide; however, the claimed peptide cannot be a hematopoietic stem cell growth. The structure suggests the peptide is capable of being an activity. Applicants should insert peptide after growth to better clarify that the claim is drawn to a "hematopoietic stem cell growth peptide."

Claims 9 and 15 are rejected wherein it is unclear if applicants are claiming promotion of stem cell survival and either myeloid or megakaryocytic differentiation or stem cell survival and both myeloid and megakaryocytic differentiation.

Claims 11-14 are rejected for depending from rejected claims.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., the peptides comprising an amino acid sequence "derived" from the C-terminal region of the read-through variant of acetylcholinesterase as denoted by SEQ ID NO: 1. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of

a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There are no specifically indicated species of the claimed genus disclosed that are within the scope of the claimed genus, *i.e.* peptides comprising amino acid sequence substantially as denoted by SEQ ID NO: 1. The disclosure of one or two species may provide an adequate written description of a genus when the species disclosed are representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the numerously possible species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of peptides comprising amino acid sequence substantially as denoted by SEQ ID NO: 1. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
01December 2003

BRENDA BRUMBACK
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